

PTO/SB/08A (10-01)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet

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of

19

**Complete if Known**

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Sharon L. Turner <i>McMichael</i>
Attorney Docket Number	15270J-004761US

**U.S. PATENT DOCUMENTS**

Examiner	Cite No.	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
<i>CS</i>	305	09/724,842	11-28-2000	Chalifour et al.	
<i>CS</i>	283	09/441,140	11-18-1999	Solomon et al.	
	242	60/468,594	N/A	Chalifour et al.	
	262	60/159,887	N/A	Chen	
	295	60/184,504	N/A	Holtzman et al.	
	299	60/180,295	N/A	Rasmussen et al.	
	306	60/254,465	N/A	Holtzman et al.	
	267	60/254,499	N/A	Holtzman et al.	
<i>CS</i>	326	2002/0136718 A1	09-26-2002	Raso	
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	300	2001/0018053 A1	08-30-2001	McMichael	
	306	6,417,178 B1	07-09-2002	Klunk et al.	
	267	6,294,171 B2	09-25-2001	McMichael	
	234	6,284,221 B1	09-04-2001	Schenk, et al.	
	230	6,262,335 B1	07-17-2001	Hsiao et al.	
	231	6,114,133	09-05-2000	Seubert et al.	
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	1	6,067,367	05-02-2000	Stamler et al.	
	221	5,989,566	11-23-1999	Cobb et al.	
	2	5,958,883	09-28-1999	Snow	
	3	5,955,317	09-21-1999	Suzuki et al.	
	4	5,955,079	09-21-1999	Mond et al.	
	5	5,877,399	03-02-1999	Hsiao et al.	
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	9	5,851,996	12-22-1998	Kline	
	10	5,849,298	12-15-1998	Weiner et al.	
	321	5,837,872	11-17-1998	Schenk et al.	
	11	5,837,473	11-17-1998	Maggio et al.	
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<i>CS</i>	207	5,780,597	07-14-1998	Potter	
	13	5,753,624	05-19-1998	McMichael et al.	

Examiner  
Signature*McMichael*Date  
Considered

5/9/03

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<sup>2</sup> Applicant's unique citation designation number (optional). <sup>3</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>4</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>7</sup> Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2

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**Complete If Known**

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Sharon L. Turner <i>Wichit</i>
Attorney Docket Number	15270J-004761US

14	5,750,349	05-12-1998	Suzuki et al.
197	5,744,368	04-28-1998	Goldhaber et al.
211	5,736,142	04-07-1998	Sette et al.
15	5,733,547	03-31-1998	Weiner et al.
16	5,686,651	11-18-1997	Solomon
17	5,679,348	10-21-1997	Nesburn et al.
18	5,645,820	07-08-1997	Hafler et al.
19	5,641,474	06-24-1997	Hafler et al.
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21	5,612,486	03-18-1997	McConlogue et al.
22	5,605,811	02-25-1997	Seubert et al.
320	5,593,846	01-14-1997	Schenk et al.
23	5,585,100	12-17-1996	Mond et al.
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34	4,666,829	05-19-1987	Glenner et al.

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
<i>JS</i>	35	EP	911 036	A2	04-28-1999			
<i>JS</i>	36	EP	868 918	A2	10-07-1998			
<i>JS</i>	37	EP	863 211	A1	09-09-1998			
<i>JS</i>	38	EP	845 270	A1	08-03-1998			

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 801.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 3 of 19

**Complete if Known**

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Sharon L. Turner <i>Nichols</i>
Attorney Docket Number	15270J-004761US

39	EP	782 859	A1	07-09-1997			
40	EP	683 234	A1	11-22-1995			
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44	EP	613 007	A2	08-31-1994			
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50	EP	440 619	B1	01-24-1996			
51	EP	359 783	B1	11-29-1995			
52	EP	276 723	B1	12-08-1993			Yes
187	EP	783 104	A1	07-09-1997			
284	PCT	01/62801	A2	08-30-2001			
301	PCT	01/62284	A2	03-01-2000			
298	PCT	01/42306	A2	06-14-2001			
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324	PCT	00/72870	A1	12-07-2000			
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188	PCT	00/43049	A1	07-27-2000			
53	PCT	99/60024	A1	11-25-1999			
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56	PCT	99/08066	A2	02-11-1999			
57	PCT	99/27949	A1	06-10-1999			
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59	PCT	99/27911	A1	06-10-1999			
203	PCT	99/00150	A2	01-07-1999			
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61	PCT	98/07850	A2	02-26-1998			
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Sheet 4 of 19

**Complete if Known**

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Sharon L. Turner <i>NICHOLS</i>
Attorney Docket Number	15270J-004761US

63	PCT	96/39176	A1	12-12-1996	
208	PCT	96/28471	A1	09-19-1996	
64	PCT	96/25435	A1	08-22-1996	
65	PCT	96/18900	A1	08-20-1996	
66	PCT	95/31996	A1	11-30-1995	
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68	PCT	95/11311	A1	04-27-1995	
227	PCT	95/11008	A2	04-27-1995	
69	PCT	95/05853	A1	03-02-1995	
70	PCT	95/04151	A2	02-09-1995	
201	PCT	94/28412	A1	12-08-1994	
71	PCT	94/03615	A1	02-17-1994	
72	PCT	94/01772	A1	01-20-1994	
73	PCT	93/21950	A1	11-11-1993	
74	PCT	93/16724	A1	09-02-1993	
75	PCT	93/15760	A1	08-19-1993	
76	PCT	93/14200	A1	07-22-1993	
205	PCT	93/04194	A1	03-04-1993	
77	PCT	93/02189	A1	02-04-1993	
78	PCT	92/13089	A1	08-08-1992	
79	PCT	92/08708	A1	04-30-1992	
80	PCT	92/08187	A1	04-16-1992	
81	PCT	91/19810	A1	12-26-1991	
82	PCT	91/16819	A1	11-14-1991	
83	PCT	91/12816	A1	09-05-1991	
84	PCT	91/08760	A1	08-27-1991	
85	PCT	90/12871	A1	11-01-1990	
86	PCT	90/12870	A1	11-01-1990	
87	PCT	89/01343	A1	02-23-1989	
88	PCT	89/06242	A1	07-13-1989	
89	PCT	89/06689	A1	07-27-1989	
90	PCT	89/03657	A1	05-05-1989	
91	PCT	88/10120	A1	12-29-1988	
92	GB	2 220 211	A	01-04-1990	
93	GB	2 335 192	A	09-15-1999	

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Sheet 6

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19

**Complete If Known**

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Sharon L. Turner- <b>NICHOLS</b>
Attorney Docket Number	15270J-004761US

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
<b>ASU</b>	94	ANDERSEN et al., "Do nonsteroidal anti-inflammatory drugs decrease the risk for Alzheimer's disease?", <i>Neurology</i> , 48:1441-1445 (1995).	<input type="checkbox"/>
	95	Associated Press, "Immune cells may promote Alzheimer's, a study finds," <i>The Boston Globe</i> (4/13/95).	<input type="checkbox"/>
	176	BARD et al., "Peripherally administered antibodies against amyloid $\beta$ -peptide enter the central nervous system and reduce pathology in a mouse model of Alzheimer disease," <i>Nature Medicine</i> , 6(8):916-919 (2000).	<input type="checkbox"/>
	228	BARROW, et al., "Solution Conformations and aggregational Properties of Synthetic Amyloid Beta-Peptides of Alzheimer's Disease. Analysis of Circular Dichroism Spectra" <i>J. Mol. Biol.</i> , 225(4): 1075-1093 (1992).	<input type="checkbox"/>
	96	BAUER et al., "Interleukin-6 and $\alpha$ -2-macroglobulin indicate an acute-phase state in Alzheimer's disease cortices," <i>FEBS Letters</i> , 285(1):111-114 (1991).	<input type="checkbox"/>
	239	BEASLEY, "Alzheimer's traced to proteins caused by aging," Reuters, April 20, 2001 7:56 PM ET.	<input type="checkbox"/>
	204	BERCOVICI et al., "Chronic Intravenous Injections of Antigen Induce and Maintain Tolerance in T Cell Receptor-Transgenic Mice," <i>Eur. J. Immunol.</i> 29:345-354 (1999).	<input type="checkbox"/>
	212	BICKEL et al., "Site Protected, Cationized Monoclonal Antibody Against Beta Amyloid as a Potential Diagnostic Imaging Technique for Alzheimer's Diseases," <i>Soc. for Neuroscience Abstracts</i> 18:764 (1992).	<input type="checkbox"/>
	97	BLASS, John P., "Immunologic Treatment of Alzheimer's Disease," <i>New England J. Medicine</i> , 341(22):1694 (1999).	<input type="checkbox"/>
	98	BODMER et al., "Transforming Growth Factor-Beta Bound to Soluble Derivatives of the Beta Amyloid Precursor Protein of Alzheimer's Disease," <i>Biochem. Biophys. Res. Comm.</i> , 171(2):890-897 (1990).	<input type="checkbox"/>
	99	BORCHELT et al., "Accelerated Amyloid Deposition in the Brains of Transgenic Mice Coexpressing Mutant Presenilin 1 and Amyloid Precursor Proteins," <i>Neuron</i> , 19: 939-945 (1997).	<input type="checkbox"/>
<b>ASU</b>	100	BORIS-LAWRIE et al., "Recent advances in retrovirus vector technology," <i>Curr. Opin. Genet. Develop.</i> , 3: 102-109 (1993).	<input type="checkbox"/>

Examiner  
SignatureDate  
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Art Unit	1847
Examiner Name	Sharon L. Turner <b>NICHOLS</b>
Attorney Docket Number	15270J-004781US

CSW	101	BRICE et al., "Absence of the amyloid precursor protein gene mutation (APP717 Val>Ile) in 85 cases of early onset Alzheimer's disease," <u>J. Neurology, Neurosurg. Psychiatry</u> , 56:112-115 (1993).	<input checked="" type="checkbox"/>
↓	327	CAMERON, "Recent Advances in Transgenic Technology," <u>Molecular Biotechnology</u> , 7:253-265 (1997).	<input type="checkbox"/>
CSW	285	CAPUTO et al., "Therapeutic approaches targeted at the amyloid proteins in Alzheimer's disease," <u>Clin. Neuropharm.</u> , 15:414A-414B (1992).	<input type="checkbox"/>
	224	Center for Biological Evaluation and Research, U.S. Food and Drug Administration, Thimerosal in Vaccines (Mercury in Plasma-Derived Products), web site contents found at: <a href="http://www.fda.gov/centerforvaccines/thimerosal.htm">http://www.fda.gov/centerforvaccines/thimerosal.htm</a> , last updated May 16, 2002.	<input type="checkbox"/>
CSW	102	CHAO et al., "Transforming Growth Factor- $\beta$ Protects human Neurons Against $\beta$ -Amyloid-Induced Injury," <u>Soc. Neurosci. Abstracts</u> , 19:513-7 (1993).	<input checked="" type="checkbox"/>
CSW	266	CHAPMAN, PAUL F., "Model behavior," <u>Nature</u> , 408:915-916 (2000).	<input type="checkbox"/>
	222	Chemical Abstract database, Abstract of "Injection of Newborn Mice with Seven Chemical Adjuvants to Help Determine Their Safety in Use in Biologics," Chemical Abstract database. (Publication date unknown.)	<input type="checkbox"/>
CSW	307	CHEN, et al. A learning deficit related to age and beta-amyloid plaques in a mouse model of Alzheimer's disease. <u>Nature</u> , 408(6815):975-9 (2000).	<input type="checkbox"/>
	213	CHEN et al. "An Antibody to $\beta$ Amyloid Precursor Protein Inhibits Cell-substratum Adhesion in Many Mammalian Cell Types," <u>Neuroscience Letters</u> 125:223-226 (1991).	<input type="checkbox"/>
	302	CHUNG et al. "Uptake, Degradation, and Release of Fibrillar and Soluble Forms of Alzheimer's Amyloid $\beta$ -Peptide by Microglial Cells," <u>J. Biol. Chem.</u> , 274(45):32301-32308 (1999).	<input type="checkbox"/>
	291	COLOMA et al., "Transport Across the Primate Blood-Brain Barrier of a Genetically Engineered Chimeric Monoclonal Antibody to the Human Insulin Receptor," <u>Pharm. Res.</u> , 17:268-274 (2000).	<input type="checkbox"/>
	286	CORDELL, B., " $\beta$ -Amyloid formation as a potential therapeutic target for Alzheimer's disease," <u>Ann. Rev. Pharmacol. Toxicol.</u> , 34:69-89 (1994).	<input type="checkbox"/>
↓	287	COSTA et al., "Immunoassay for transthyretin variants associated with amyloid neuropathy," <u>Scand. J. Immunol.</u> , 38:177-182 (1993).	<input type="checkbox"/>
CSW	293	DALY, et al., "Detection of the membrane-retained carboxy-terminal tail containing polypeptides of the amyloid precursor protein in tissue from Alzheimer's Disease brain," <u>Life Sci.</u> , 63:2121-2131 (1998).	<input type="checkbox"/>

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SignatureDate  
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 7

of 19

**Complete if Known**

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1847
Examiner Name	Sharon L. Turner <i>NICHOLS</i>
Attorney Docket Number	15270J-004761US

<i>CSN</i>	214	DEMATIOS et al., "Peripheral Anti A $\beta$ Antibody Alters CNS And Plasma A $\beta$ Clearance and Decreases Brain A $\beta$ Burden in a Mouse Model of Alzheimer's Disease," <i>Proc. Natl. Acad. Sci. USA</i> , 10.1073/pnas.151261398 (2001).
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Sheet 8 of 19

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Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1847
Examiner Name	Sharon L. Turner <i>NICHOLS</i>
Attorney Docket Number	15270J-004761US

<i>DN</i>	108	FLANDERS et al., "Altered expression of transforming growth factor- $\beta$ in Alzheimer's disease," <u>Neurology</u> , 45:1551-1559 (1995).
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Sheet 9 of 19

**Complete if Known**

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1847
Examiner Name	Sharon L. Turner <b>NICHOLS</b>
Attorney Docket Number	15270J-004781US

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**Complete If Known**

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1847
Examiner Name	Sharon L. Turner <i>NICHOLS</i>
Attorney Docket Number	15270J-004761US

<i>gso</i>	118	HAGA et al., "Synthetic Alzheimer amyloid $\beta$ /A4 peptides enhance production of complement C3 component by cultured microglial cells," <u>Brain Research</u> , 601:88-94 (1993).
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 11

of 19

## Complete if Known

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Sharon L. Turner <i>NICHOLS</i>
Attorney Docket Number	15270J-004761US

<i>CS</i>	258	IKEDA, et al., "Immunogold labeling of cerebrovascular and neuritic plaque amyloid fibrils in Alzheimer's disease with an anti- $\beta$ protein monoclonal antibody," <i>Lab. Invest.</i> , 57:446-449 (1987).	
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<i>CS</i>	129	LAMPERT-ETCHELLS et al., "Regional Localization of Cells Containing Complement C1q and C4 mRNAs in the Frontal Cortex During Alzheimer's Disease," <i>Neurodegeneration</i> , 2:111-121 (1993).	
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Examiner  
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 12

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19

## Complete if Known

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Sharon L. Turner <b>NICHOLS</b>
Attorney Docket Number	15270J-004761US

CSO	131	LANNFELT et al., "Alzheimer's disease: molecular genetics and transgenic animal models," <u>Behavioural Brain Res.</u> 57:207-213 (1993).
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Sheet 13 of 19

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Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1847
Examiner Name	Sharon L. Turner <b>NICKUS</b>
Attorney Docket Number	15270J-004761US

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Sheet 14

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**Complete if Known**

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Sharon L. Turner <i>NICHOLS</i>
Attorney Docket Number	15270J-004761US

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Examiner Signature <i>[Signature]</i>		Date Considered 5/9/03

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First Named Inventor	Dale B. Schenk
Art Unit	1847
Examiner Name	Sharon L. Turner <b>NICHOLS</b>
Attorney Docket Number	15270J-004761US

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**Complete If Known**

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Sheron L. Turner <b>NICHOLS</b>
Attorney Docket Number	15270J-004761US

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Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1847
Examiner Name	Sharon L. Turner <i>NIC HOLS</i>
Attorney Docket Number	15270J-004761US

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**Complete If Known**

Application Number	09/724,562
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
An Unit	1647
Examiner Name	Sharon L. Turner <i>NICHOLS</i>
Attorney Docket Number	15270J-004761US

<i>CDW</i>	167	VAN GOOL et al., "Concentrations of amyloid- $\beta$ protein in cerebrospinal fluid increase with age in patients free from neurodegenerative disease," <i>Neuroscience Letters</i> , 172:122-124 (1994).
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Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Sharon L. Turner <i>Nichols</i>
Attorney Docket Number	15270J-004761US

<i>CS</i>	292	YAMAGUCHI et al., Diffuse plaques associated with astroglial amyloid $\beta$ protein, possibly showing a disappearing stage of senile plaques, <i>Acta Neuropathol.</i> , 95:217-222 (1998).	
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3

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3

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Application Number	09/724,552
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First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Sharon L. Turner - Nichols
- Attorney Docket Number	15270J-004761US

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First Named Inventor	Dale B. Schenk
Art Unit	1847
Examiner Name	Sharon L. Turner NICHOLS
Attorney Docket Number	15270J-004761US

**U.S. PATENT DOCUMENTS**

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**Complete If Known**

Application Number	09/724,552
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Sharon L. Turner <b>NICHOLS</b>
Attorney Docket Number	15270J-004761US

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

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<b>CS</b>	332	CHEN, et al., "Neurodegenerative Alzheimer-like pathology in PDAPP 717V→F transgenic mice," <u>Progress in Brain Research</u> , Van Leeuwen et al. Eds, 117:327-337 (1998).	
	333	CONWAY et al., "Acceleration of oligomerization; not fibrillization; is a shared property of both $\alpha$ -synuclein mutations linked to early-onset Parkinson's disease: Implications for pathogenesis and therapy," <u>PNAS</u> , 97(2):571-576 (2000)	
	334	JOBLING and HOLMES, "Analysis of structure and function of the B subunit of cholera toxin by the use of site-directed mutagenesis," <u>Molecular Microbiology</u> , 5(7):1755-1767 (1991).	
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<b>CS</b>	337	SKOLNICK and FETROW, "From genes to protein structure and function: novel applications of computational approaches in the genomic era," <u>Trends in Biotech.</u> , 18(1):34-39 (2000).	

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